

AMENDMENTS TO THE SPECIFICATION

Please replace the paragraph beginning at page 11, line 3, with the following amended paragraph:

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Figure 2 ~~[[is]]~~ illustrates an additional embodiment of the present invention utilizing a tapered distal portion of the probe. The probe 32 ~~has a~~ distal portion ~~32~~ also 33 ~~which~~ includes a series of recessed vanes 34 connected to at least one internal lumen (not shown) to stabilize tissue. An additional port 36 may be used to deploy or receive a plurality of fastening devices.

Please replace the paragraph beginning at page 11, line 7, with the following amended paragraph:

Figure 2a shows an illustrative valve repair procedure using the probe 32 of Figure 2 approaching the tissue from the arterial side 30 ~~portion~~ of the valve ~~[[30]]~~, while additionally stabilizing the tissue with probe 10b from the ventricular side 31 ~~portion~~ of the valve. The port 36 at the distal tip of the nose ~~[[36]]~~ is exposed to the ventricular 31 side of the leaflets 14 and 16. Because of this exposure, various leaflet fastening devices can be delivered through the probe ~~[[34]]~~ 32 to the ventricular 31 side of the leaflets 14 and 16, as will be detailed below. Likewise, a tissue fastening device may be deployed by probe 10b through the leaflets, 14 and 16, to the probe ~~[[34]]~~ 32 positioned proximal to the arterial portion of the mitral valve. Interference with the stabilization process by guidewire 12 is negligible. Those skilled in the art will appreciate either the antegrade probe, the retrograde probe, or both, may utilize the tapered nose design detailed herein.

Please replace the paragraph beginning at page 11, line 26 with the following amended paragraph:

In Figure 3b, a tissue stabilizer 52 includes a flat distal face 54 disposing at least two guidewire ports 55a and 55b, and having a single distally-directed tissue separating wall 56 extending therefrom. The stabilizer 52 contains one or more lumens in communication with circular vacuum ports 58a and 58b (not shown) that open on either side ~~both sides~~ of the wall 56.

Please replace the paragraph beginning at page 11, line 30 with the following amended paragraph:

a2 In Figure 3c, a tissue stabilizer 60 includes a flat distal face 62, disposing at least two guidewire ports 63a and 63b radially positioned about distal face 62, and having a single distally-directed tissue separating wall 64 extending therefrom. The stabilizer 60 contains one or more lumens in communication with semi-circular vacuum ports 66a (not shown) and 66b that open on both sides of the wall 64. There are two such ports 66a (not shown) and 66b, one on each side of each wall 64.

Please replace the paragraph beginning at page 14, line 12 with the following amended sentence:

a3 Figures 8a-8c illustrate a tissue stabilizing and fastening device 130a-b having needles 132 deployable on a blind side of the tissue by the retrograde probe 130b. A common suture thread 134 connects the needles 132 and is used to secure the tissue pieces [[714]] 14 and 16 together. Thus, as seen in the sequence of Figures 8a-8c, the needles 132 are first advanced to a position proximate the tissue pieces 14 and 16 and deployed outboard of the distal tip of the retrograde probe 130b. Once positioned, the needles are advanced through the tissue, as in Figure 8a, to cause the needles 132 to pierce the tissue pieces 14 and 16. The two needles 132 are then disengaged from the device 130b, and each other, as in Figure 8b, and antegrade probe 130a captures the needles 132 from the pieces 14 and 16, leaving the connected suture joining the two

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pieces 14 and 16 (Figure 8c). The suture 132 can then be tied off, or otherwise secured on the upper side of the tissue pieces 14 and 16.

Please replace the paragraph beginning at page 14, line 24 with the following amended paragraph:

Figure 9a shows an exemplary tissue staple 280 for joining two tissue pieces in an open configuration. The staple 280 includes a bridge portion 282 and four gripping arms [[244]] 284, two on each side. The gripping arms 284 are initially curled in a semi-circle upward from the plane of the bridge portion 282 and terminate in sharp points approximately in the plane of the bridge portion 282. Figure 9b shows the staple 280 when closed, with the gripping arms 284 curled underneath the plane of the bridge portion 282 toward each other.

Please replace the paragraph beginning at page 14, line 30 with the following amended paragraph:

Figures 10a-10c illustrate several steps in a valve repair procedure using an exemplary tissue fastening device 290 for delivering the tissue staple 280. As with the previous embodiments, a retrograde probe (not shown) is utilized to stabilize the tissue prior to and during deployment of the fastening device. Additionally, the retrograde probe (not shown) may be used as an anvil or stop-body to assist in closing the fastener. The device 290 includes a probe 292 with an internal lumen 294 within which a pusher 296 is slidable, and having at least two guidewire ports (not shown) positioned radially about the distal portion of the probe. A stop member 298 is also provided underneath the bridge portion 282 of the staple 280 to prevent displacement of the bridge portion 282 toward the leaflets [[22]] 14 and 16. The probe is positioned proximate the tissue under repair. After stabilizing the leaflets [[22]] 14 and 16, the pusher 296 displaces downward which causes the staple 280 to undergo a plastic deformation from the configuration of Figure 10a to that of Figure 10b. The sharp points of the gripping arms 284 pass through

the leaflets ~~[[22]]~~ 14 and 16 and anchor the staple 280 therein. Finally, the stop member 298 is disengaged from under the bridge portion 282, and the device 290 is retracted.

Please replace the paragraph beginning at page 15, line 27 with the following amended paragraph:

Figure 12 shows an antegrade probe of the antegrade and retrograde probe system of the present invention that uses a vacuum to hold two tissue pieces 514 and 516, respectively. In this case, the tissue pieces are heart valve leaflets, 514 and 516, and a valve repair procedure using an arterial probe 512a and a ventricular probe 512b (not shown). Probes 512a and 512b will hereinafter be generically described as probe 512. As shown in Figure 12, the probe 512 comprises a cylindrical probe body 518 with at least one internal lumen (not shown) and having a tapered distal portion 520 disposing at least one guidewire port (not shown) and at least one vacuum port ~~[[.]]~~ 524. At least one deployable alignment mechanism 523 is positioned proximate the probe distal portion 520 and ~~[[are]]~~ is in communication with the handpiece (not shown) by a deployment conduit (not shown) positioned in at least one internal lumen (not shown) contained within probe 512. Once the probe 512 is positioned proximate to the tissue 514 and 516, respectively, the deployable alignment mechanism 523 is deployed and interacts with the surrounding tissue. The external vacuum source (not shown) is then activated. The at least one vacuum port 524 stabilizes tissue pieces 514 and 516. Upon completion of the procedure, ~~deployable tissue fasteners are~~ the deployable alignment mechanism 523 is retracted to facilitate removal of the probe 512. While Figure 12 shows the deployable alignment mechanism disposed on an antegrade probe, either the antegrade probe, the retrograde probe, or both, may include deployable alignment devices.

Please replace the paragraph beginning at page 17, line 4 with the following amended paragraph:

OS Figures 14a-14b show a mitral valve procedure being performed by the present invention. Antegrade probe (not shown) is positioned proximate the arterial portion of the mitral tissue 542a and 542b by guidewires (not shown). The retrograde probe 540b is positioned proximate the ventricular portion of the mitral tissue 542a and 542b, and is similarly directed by the guidewires. Retrograde probe 540b further disposes a steering sleeve 546 containing an actuated support 548 which is connected to a steering sleeve conduit 550 which is positioned within an internal lumen located in the probe 540b. The probe 540b and steering sleeve conduit 550 are positioned proximate the tissue under repair. Once positioned, probe ~~[[540]]~~ 540b is advanced while the steering sleeve ~~conduit~~ 546 is held stationary. Advancement of the probe ~~[[540]]~~ 540b results in extension of the actuated support 548 thereby positioning probe 540b ~~[[m]]~~ more proximate the tissue under repair.

Please replace the paragraph beginning at page 17, line 16 with the following amended paragraph:

Figure 15 shows a mitral valve procedure being performed by the present invention. Antegrade probe (not shown) is positioned proximate the arterial portion of the mitral tissue 552a and 552b by guidewires (not shown). The retrograde probe 554b is positioned proximate the ventricular portion of the mitral tissue 552a and 552b, and is similarly directed by the guidewires. Retrograde probe 554b further disposes at least one biasing joint containing at least one balloon which is connected to an inflation conduit (not shown) positioned within an internal lumen located in the probe 554b. Figure 15 shows a probe 554b disposing 3 biasing joints 556a, 556b, and 556c, each containing a steering balloon 558a, 558b, and 558c, respectively. The probe 554b is positioned proximate the tissue under repair. Once positioned, steering balloons 558a, 558b, and 558c are inflated thereby articulating the distal portion of the probe 554b at an angle proximate the tissue.

Please replace the paragraph beginning at page 17, line 28 with the following amended paragraph:

The present invention may be adapted to sequentially stabilize a portion of tissue and deploy a tissue fastening device therein. As shown in Figure 16a, a first antegrade probe 564a is advanced along at least one guidewire 562 to a position proximate the tissue to be repaired 566a and 566b. The first antegrade probe 564a comprises a vacuum port 568 in fluid communication with a vacuum lumen 570 and a tissue fastening device ~~[[572]]~~ 572a located within the probe 564a. The tissue fastening device ~~[[572]]~~ 572a may include fastener deployment mechanisms and fasteners disclosed above. A retrograde probe 564b, which is used to position and stabilize the antegrade probe, is advanced along the at least one guidewire 562 to a position proximate the retrograde portions of the tissue. With the probes 564a and 564b positioned, a single portion of tissue 566a is captured by the vacuum port 568 disposed on the first antegrade probe 564a. A fastening device 572a is deployed through the single portion of tissue 566a. The first antegrade probe 564a disengages the tissue 566a and the retrograde probe 564b, and is thereafter removed. Figure 16b shows a second antegrade probe 564c comprising a vacuum port 574 in fluid communication with a vacuum lumen 576, and a tissue fastening device 572b located within the probe 564c is advanced to a position proximate the tissue 566a and 566b. Like the first antegrade probe 564a, the second antegrade probe 564c is adapted to engage the retrograde probe 564b, and deploy a tissue fastener. Once the probes are positioned, the vacuum port 574 disposed on the second ~~retrograde~~ antegrade probe 564c captures tissue portion 566b. A tissue fastener 572b is deployed into the tissue. The second antegrade probe 564c disengages the tissue 566b, and the second antegrade probe 564c and ~~retrograde~~ retrograde probe 564b are removed. As shown in Figure 16c, the tissue fastening device is joined, for example, by tying, thereby repairing the tissue. Like the previous embodiments the probes 564a, 564b, and 564c may include additional internal lumens.